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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/027,015      | 12/21/2001  | Rama Akella          | 2103.000500         | 1147             |

45488 7590 03/14/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/027,015

Applicant(s)

AKELLA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 20-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-6 and 20-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-6 and 20-40 are pending.

Applicants' amendment and response filed October 24, 2005 is acknowledged.

Applicants' response has been fully considered. Claims 1-5 have been amended, claims 7-19 have been cancelled, and new claims 20-40 have been added. Applicant has elected SEQ ID NO:4 in the response to restriction requirement filed July 5, 2005, however, since the sequence GGIGDGG (SEQ ID NO:2) was mistakenly cited as SEQ ID NO:4 in the previous claims, now being corrected. Therefore, claims 1-6 and 20-40 and SEQ ID NO:2 are examined.

### **Withdrawn Informalities**

2. The previous objection to the specification, regarding the sequence of GGDIGGG, is withdrawn in view of applicant's submission of a new paper copy and computer readable form (CRF) of the sequence listing, and applicant's response at page 8 of the amendment filed October 24, 2005. CRF has been entered.

3. The previous objection to the specification, regarding the drawings and missing application number of a co-pending application, is withdrawn in view of applicant's amendment to the drawings and specification, and applicant's response at page 8 of the amendment filed October 24, 2005.

### **Withdrawn Claim Objections**

4. The previous objection to claims 2-5, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 9 of the amendment filed October 24, 2005.

**Withdrawn Claim Rejections - 35 USC § 112**

5. The previous rejection of claims 1-7 under 35 U. S. C. 112, second paragraph, regarding the sequence of GGDIGGG being SEQ ID NO:4, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 9 of the amendment filed October 24, 2005.

**Withdrawn Claim Rejections - 35 USC § 103**

6. The previous rejection of claims 1 and 5-7 under 35 U. S. C. 103(a) as being unpatentable over Schor (WO99/02674), is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 10 of the amendment filed October 24, 2005.

***Informalities***

The disclosure is objected to because of the following informalities:

7. The specification cites a sequence of GGIGD at page 9, line 17, it appears the sequence is GGIGDGG (SEQ ID NO:2). Appropriate correction is required.

***Claim Objections***

8. Claim 6 is objected to because the claim recites a pharmaceutically acceptable carrier being included in the composition in addition to the components cited in claim 5 (i.e., at least one peptide including the sequence of GGIGDGG (SEQ ID NO:2) and a matrix material). Therefore, for clarity, the use of the term "further comprising" is suggested. Please see also claims 23, 26, 29 and 34.

9. Claims 22 and 33 are objected to because the claim contains recitation of non-elected sequences. Appropriate correction is required.

*New Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2-6 and 20-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-6 and 20-40 are directed to an angiogenic composition comprising at least one peptide including (read as comprising) the sequence of GGIGDGG (SEQ ID NO:2) and at least one angiogenic growth factor; or composition that is active for promoting cell migration and/or angiogenesis under cell growth promoting conditions, the composition comprising at least one peptide including the sequence of GGIGDGG (SEQ ID NO:2) and a matrix material, where the composition may further comprise at least one angiogenic growth factor. While the specification discloses an angiogenic composition comprising at least one of the peptides of SEQ ID NO:1-6 and Formula 1 (ZZIGDZZ, Z is any of the twenty amino acids), and at least one angiogenic growth factor (page 4, lines 24-32); or a composition comprising a protein having (read as comprising) angiogenic activity and the amino acid sequence of SEQ ID NO:2 (page 4, lines 3-5), it does not identify any protein having angiogenic activity and comprising the amino acid sequence of SEQ ID NO:2 except for the sequence of SEQ ID NO:2. The specification only discloses the sequence of SEQ ID NO:2 exhibiting angiogenic activity (Examples 1-3), it does

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not describe a genus of variants for peptides (with different length or sequence) comprising the sequence of SEQ ID NO:2 and having angiogenic activity. Without guidance on the structure to function/activity relationship for various peptides containing SEQ ID NO:2, one skilled in the art would not know which peptide containing SEQ ID NO:2 is functional. The lack of description on the structure to function/activity relationship of the peptides containing SEQ ID NO:2 and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

11. Claims 22 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 22 and 33 are directed to an angiogenic composition comprising at least one peptide including the sequence of GGIGDGG (SEQ ID NO:2) and at least one angiogenic growth factor, optionally containing a matrix material, wherein at least one angiogenic growth factor comprises at least one peptide of SEQ ID NO:1-5 or 6. While the specification discloses an angiogenic composition comprising at least one of the peptides of SEQ ID NO:1-6 and Formula 1 (ZZIGDZZ), and at least one angiogenic growth factor, wherein the at least one angiogenic growth factor is a bone-derived angiogenic proteins (BDAPS), vascular endothelial cell growth factor (VEGF), basic fibroblast growth factor (bFGF), angiogenin, endothelial growth factor (EGF), platelet derived growth factor (PDGF), transforming growth factor-alpha

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(TGF- $\alpha$ ), transforming growth factor-beta (TGF- $\beta$ ), and tumor necrosis factor-alpha (TNF- $\alpha$ ); or a composition comprising a protein having angiogenic activity and the amino acid sequence of SEQ ID NO:2 (page 4), it does not disclose the at least one angiogenic growth factor comprises at least one peptide of SEQ ID NO:1-5 or 6. The specification does not indicate the listed angiogenic growth factor such as BDAPS, VEGF, bFGF, angiogenin, EGF, PDGF, TGF- $\alpha$ , TGF- $\beta$ , and TNF- $\alpha$  contains the sequence of SEQ ID NO:1-6. The lack of description on the angiogenic growth factor comprising the sequence of SEQ ID NO:1-5 or 6, and lack of representative species, one skilled in the art would not know how to identify these fibers. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 4, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 4 is indefinite because the claim does not further limit claim 3. Claim 3 recites other at least one angiogenic growth factor is chosen from “the group consisting of “BDAPS.....and TNF- $\alpha$ , which is a closed language, while claim 4 recites the term “comprising”, which is an open language.

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14. Claims 27 and 28 recites the limitation "the injectable solution" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

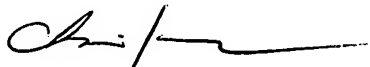
15. Claims 2-6 and 20-40 are rejected; it appears that claim 1 is free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM  
PATENT EXAMINER**

CMK

March 10, 2006